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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,538	03/26/2001	Zuomei Li	106101.144	6847

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EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,538

Applicant(s)

LI ET AL.

Examiner

Mary M. Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-3, 5 and 7 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 lacks antecedent basis since it is dependent on canceled claim 6. For the purposes of the instant Office action and rejections below, claim 7 is considered dependent on claim 1 since canceled claim 6 was previously dependent on claim 1.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 5 and 7 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/817,913. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reasons of record set forth in the Official action mailed 8/6/02.

Applicant's arguments filed 2/14/03 have been fully considered but they are not persuasive.

Claim 1 was amended to recite that the oligonucleotide is from 15 to about 26 nucleotides. This amendment does not change the rejection since the rejection stated that it would have been obvious to make an antisense to instant SEQ ID NO:2 having 20-26 nucleotides

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in length as stated in the previous rejection, and thus the obvious range of size remains within the instantly claimed antisense length. Also, claim 7 is interpreted to be dependent on claim 1 for the purposes of the instant rejection.

Applicants defer filing of a Terminal Disclaimer until such time that the claims in one or the other applications are otherwise found allowable. Since applicants have not further argued on the merits the instant rejection, the rejection stands.

Claim Rejections - 35 USC 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (IDS reference A3, IDS filed 10/09/01) in view of the collection of Taylor et al. (*DDT* Vol. 4, No. 12, 12/12/99, pages 562-567), Bennett et al. (Chapter 2, pages 13-46, from Methods in Molecular Medicine: Antisense Therapeutics, 1996), Baracchini et al. (U.S. Patent 5,801,154) and Cowser et al. (U.S. Patent 5,951,455) and the sequence of HDAC01 (instant SEQ ID NO:2 from GenBank Accession No. U50079, Applicants own admission, page 9 of specification) for the same reasons of record set forth in the Official action mailed 8/6/02.

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Applicant's arguments filed 2/14/03 have been fully considered but they are not persuasive.

Claim 1 was amended to recite that the oligonucleotide is from 15 to about 26 nucleotides. This amendment does not change the rejection since the rejection stated that it would have been obvious to make an antisense to instant SEQ ID NO:2 having about 13 to about 35 or about 15 to about 26 nucleotides in length, or having 20-26 nucleotides in length. Claim 7 is considered dependent on claim 1 for the purposes of the instant rejection as stated above.

On page 8 of the response, applicants state that “[d]ue to differences in secondary structure and even chromatin structure, not all genes can be successfully inhibited by antisense oligonucleotides. Only Applicants’ specification provides the requisite expectation of success. In addition, the requisite motivation to combine the cited references is missing. Yoshida et al. teaches that small molecule inhibitors of HDAC-1 are perfectly adequate to explore the function of HDAC. One skilled in the art would thus not be motivated by Yoshida et al. to seek out papers describing antisense experimentation.”

In response, contrary to applicants assertion that Yoshida et al. did not provide the requisite motivation to make antisense to HDAC-1, as cited in the rejection, Yoshida et al. taught that the need for “the use of a more specific and potent inhibitor of histone deacetylase... to carry out further more refined analyses”. The other references were cited to show that antisense was a commonly known and art accepted method of inhibition of a target gene in cells in cell culture and thus would have been an obvious choice for making a specific inhibitor of HDAC-1.

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Furthermore, as stated in the rejection, there would have been an expectation of success to make and use at least one antisense of the claimed length to target and inhibit the gene of instant SEQ ID NO:2 in cells in cell culture since Taylor et al., Barachini et al. and Cowser et al. all taught that it was well known in the art to make and use antisense to a known target gene for uses in cells in cell culture.

8. Claim 7 is considered free of the prior art since the prior art did not teach nor fairly suggest the sequences of instant SEQ ID NOS: 17 and 18 now that priority of these SEQ ID NOS. has been perfected to the filing of the provisional applications.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

M. M. Schmidt
May 1, 2003